

REMARKS

The Office Action has rejected Claims 20, 21, 25-34, 56, 63-67, 73-103 under 35 USC § 101, alleging that the claimed invention lacks patentable utility. Moreover, the Office Action has rejected Claims 20, 21, 25-34, 56, 63-67, and 73-103 under 35 USC § 112, first paragraph for allegedly being non-enabling. Finally, Claims 25-28, 63, 74, 88, 89 and 102 are rejected under 35 USC § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended the Claims which, when considered with the comments hereinbelow, is deemed to place the present case in condition for allowance. Favorable action is respectfully requested.

At the onset, before addressing the merits of the issues raised in the Office Action, applicant wishes to thank Examiner Lukton for the courtesy extended to his representative during the telephone interview on November 15, 2005, and for his helpful suggestions.

In support of the rejection of Claims 25-28, 63, 74, 88, 89 and 102 under 35 USC § 112, second paragraph, the Office Action alleges that the subject matter in the dependent claims relating to “EDGs” and “EWGs” is broader than that recited in independent Claim 20, upon which they are dependent.

Applicant disagrees. Since Claims 25-28, 63, 74, 88, 89 and 102 were ultimately dependent upon Claim 20 which defines the term “EWGs” and “EDGs”, it is apparent that the terms “EWGs” and “EDGs”, which appear therein, were referring to the definition in Claim 20. Nevertheless, to further emphasize that the meaning of these terms in the dependent claim is the same as in Claim 20, applicant has amended Claims 25-28, 63, 74, 88, 89 and 102 by inserting the term “said” before the terms “EWG” and “EDG”, in accordance with the Examiner Lukton’s

suggestion during the telephone interview. Such amendment does not narrow the scope of the subject matter in Claims 25-28, 63, 74, 88, 89 and 102. However, as amended, the claim recites more explicitly that the terms “EWG” and “EDG” therein refer to the definitions recited in Claim 20.

No new matter has been added to the application.

Consequently, the rejection of Claims 25-28, 63, 74, 88, 89 and 102 under 35 USC § 112, second paragraph, is obviated; withdrawal thereof is requested.

Pursuant to the rejection of Claims 20, 21, 25-34, 56, 63-67, and 73-103 under 35 USC § 101, it is apparent that the Office Action does not believe that the compounds of the present invention are useful for the prophylaxis of migraine headaches. According to the Office Action, the term prophylaxis means that headaches can be prevented with a 100% success rate in all patients.

Applicant strongly disagrees. Contrary to the allegations in the Office Action, such an interpretation is inconsistent with the definition of the term prophylaxis as used by one of ordinary skill in the art or the use of the term in the present application.

It is axiomatic that a patent specification is directed to one of ordinary skill in the art. W.L. Gore and Associates, Inc. v. Garlock, Inc., 721 F2d 1540, 1556, 220 USPQ 303, 315 (Fed Cir 1983), cert. denied, 469 US 851 (1984). In other words, the patent specification is written in terms that are understandable to one of ordinary skill in the art and not to the general public. Thus the terms, as used therein, have very definite meaning to one of ordinary skill in the art.

The term “prophylaxis”, as used in the instant application, has a specific meaning to one of ordinary skill in the art. As evidence of that meaning, applicant submits herewith an article by Silberstein in American Academy of Neurology, 2000, 1-11 (“Silberstein”). It describes, inter

alia, the accepted definition of prophylaxis as used in the art, as discussed infra. It is to be noted that this article is a report from the Quality Standards Subcommittee of the American Academy of Neurology and is not the opinion of any one person. It thus reports on the accepted definition of “prophylaxis” in this art.

Attention is directed to the definition of preventive treatment, which is defined in Page 8 of Silberstein as follows:

The goals of migraine preventive therapy are to (1) reduce attack frequency, severity and duration; (2) improve responsiveness to treatment of acute attacks; and (3) improve function and reduce disability.

This is the how the term prophylaxis is used, and understood by one of ordinary skill of the art.

A drug taken before a migraine occurs, but lessens the severity of the migraine, each time a patient suffers a migraine attack, or a drug that reduces the number of migraine attacks over time would fall within the scope of this definition. It is not necessary to have a 100% success rate of prevention as stated in the Office Action, in order to meet the requirements of this definition. Thus, the example given in the Office Action in which the drug which was administered to 1000 patients and 999 never again developed a headache falls within the scope of prophylaxis, in accordance with this definition.

Moreover, contrary to the allegations in the Office Action, it is credible that drugs are useful for the prophylaxis of migraines. As evidence thereof, attention is directed to the article by Rapoport et al in Neurol Sci 2005, 26, S111-S120 (“Rapoport et al”), which lists several drugs, which are useful for the prophylaxis of migraines. For example, Table 1 on Page S112 lists over 40 drugs and their dosage ranges, which are useful for preventive therapy for migraines. Moreover, the article discusses various types of compounds, including anti-

convulsants, which exhibit this activity. Silberstein, especially in Tables 3 and 4 therein on Pages 7 and 8, also provides examples of drugs which are useful for the prophylaxis of migraines.

In addition, there are several issued patents, which disclose the use of drugs for the prophylaxis of migraines. Listed hereinbelow are representative patents, which show that it is a credible utility for drugs to be useful for the prophylaxis of migraines. Attention, for example, is directed to U.S. Patent No. 6,841,560, disclosing substituted isoquinolines, which are also anti-convulsants, as being useful for the prophylaxis of migraines (See Column 8, Lines 32-55, to Column 9, Line 15); U.S. Patent No. 6,762,192, describing benzamide derivatives useful for the prophylaxis of migraines (See Column 6, Line 29 to Column 7, Line 50); and U.S. Patent No. 6,828,322, disclosing 1, 2, 4 -triazolo[4, 3-h] pyridazine derivatives useful for preventing migraines.

As a matter of fact, the United States Patent and Trademark Office has found such claims believable as claims have issued from the United States Patent and Trademark Office directed to the prophylaxis of migraines (See, e.g., U.S. Patent No. 6,828,322 Claim 13), U.S. Patent No. 6,762,192 (Claims 5 and 6) and U.S. Patent No. 6,841,560 (Claims 1 et seq.)

These are just a few examples, demonstrating that a claim for prophylaxis of migraines is considered credible by one of ordinary skill in the art and by the United States Patent and Trademark Office.

The Office Action argues that prophylaxis requires 100% success rate and anything less than 100% success rate shows that the compound is not useful with respect to prophylaxis. In support, it cites two articles.

As indicted hereinabove, this is not the definition of prophylaxis, as used in the art. Moreover, the passages of the two articles cited by the United States Patent and Trademark Office do not support the general proposition espoused in the Office Action.

The first article referred to in the Office Action, and especially the last paragraph of Goldstein et al, to which the Office Action makes specific reference, does not support the allegations of the Office Action that a drug useful for the prophylaxis of migraines is an incredible utility. This article relates to a study which compares three oral doses of lanepitant, a neurokinin receptor (NK-1), with a placebo in the reduction of acute migraine pain and migraine associated symptoms. The passage referred to in the Office Action indicates that “since existing acute migraine therapies are not effective in treating every migraine for any specific individual and are differentially effective between individuals, migraines may be induced and maintained by more than one mechanism.” This passage does not relate in any way to prophylaxis of migraines, and does not support the proposition that the prophylaxis of migraines is unbelievable. Moreover, this subject matter of this article is totally unrelated to the compounds described in the present application. Therefore, any conclusion drawn therein is totally irrelevant to the use of the compounds described in the present application for the prophylaxis of migraines.

Moreover, this article refers to only one compound. It is not reasonable to broaden the teachings of the Goldstein article which relates to only one NK-1 antagonist which is not effective for migraine treatment to conclude that the prophylaxis of migraines is unbelievable.

Moreover, attention is directed to the fourth page of the Goldstein article under the heading “Study Population”. In the first paragraph it refers to “patients who were on prophylactic migraine therapy”, and indicates that these patients would not make any changes to

their prophylactic dose therapy while in the study. This is an implicit admission that migraine prophylaxis is not only a believable utility, but that it is also used in practice. Thus, if anything, this article supports the utility of prophylaxis of migraines.

The passage on Page 585 of Brandes et al discloses one example of a drug that appears to be ineffective as a prophylaxis of migraines. That drug is montelukast, i.e., 1-[[[(1R)-1-[3-[(1 E)-2-(7-chloro-2-quinoliny)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]thio]methyl]cyclopropane acetic acid, an antiasthmatic. It is structurally quite different from the compounds utilized in the present invention. Even if it were true that montelukast was not useful for the prevention of migraines, as alleged in the article, based thereon, one skilled in the art could not conclude that the compounds used in the present invention could not be useful for the prophylaxis of migraines because the compounds are quite structurally different, and such a broad conclusion could not be prudently made based on just one drug. The efficacy of montelukast with respect to the prophylaxis of migraines is totally irrelevant to the issue of whether the present compounds are useful for the prophylaxis of migraines. Moreover, the findings therein are not surprising, as one of ordinary skill in the art would not expect an anti-asthmatic to be useful in migraine preventive therapy.

Thus, the United States Patent and Trademark Office has not provided any evidence to support its proposition that the compounds of the present invention are not useful for the alleged utility.

Case law has held that applicant's assertion of utility creates a presumption of utility sufficient to satisfy the utility requirement of 35 USC § 101. In re Langer, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974).

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented

must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Id., 503 F.2d at 1391, 183 USPQ at 297 (emphasis in original).

Case law has held that the Examiner has the initial burden to show that one of ordinary skill in the art would reasonably doubt the asserted utility. In re Swartz, 232 F.3d 862, 863, 56 USPQ 2d 1703, 1704 (Fed Cir 2000). Only after the Examiner has presented evidence that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince one of ordinary skill in the art of the invention's asserted utility. Id., which, in this case, is the prophylaxis of migraines. As indicated hereinabove, the United States Patent and Trademark Office has not presented evidence to support its position that the use of the compounds described in the present application for prophylaxis of migraines is unbelievable. On the other hand, applicant has provided evidence that the definition of "prophylaxis", as referred to in the Office Action is not consistent with the definition of prophylaxis as understood by one of ordinary skill in the art. Moreover, applicant has provided several examples of drugs that are useful for the prophylaxis of migraines. The United States Patent and Trademark Office has not provided any evidence which refutes that the compounds disclosed in the present application are not useful for the prophylaxis of migraines. Thus, the rejection of the claimed subject matter under 35 USC § 101, is obviated; withdrawal thereof is respectfully requested.

In support of the rejection of the claimed subject matter under 35 USC § 112, first paragraph, the Office Action reiterates its arguments. Thus, the same arguments apply to the rejection of the claims under 35 USC § 112, first paragraph, which are incorporated by reference.

Moreover, the instant application describes in detail how to use the compounds described therein for the prophylaxis of migraines. Attention is directed to Page 50, lines 25-35 which incorporates by reference the discussion on Page 43 et seq. of the instant specification. This passage describes how to prepare formulations of the compounds described in the present application for the prophylaxis of migraines and how to administer it to patients, and provides the treatment regimen in terms that are understandable to one of ordinary skill in the art. Thus, the specification provides sufficient information for one of ordinary skill in the art to utilize the compounds described in the present application for the prophylaxis of migraines without an undue amount of experimentation. Thus, contrary to the allegations in the Office Action, the application is enabling to one of ordinary skill with respect to the prophylaxis of migraines.

Therefore, for the reasons presented, the rejection of the claimed subject matter under 35 USC § 112, first paragraph, is obviated; withdrawal thereof is respectfully submitted.

Thus, in view of the Amendments to the Claims and the Remarks herein, it is respectfully submitted that the present case is in condition for allowance, which action is earnestly solicited

Respectfully submitted,



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